

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Eric A. JOHNSON et al.

Appln. No.: 08/458,019

Group Art Unit: 1651

Filed: 1 June 1995

Examiner: H. Lilling

For: PROCESS FOR IN VIVO PRODUCTION OF ASTAXANTHIN AND PHAFFIA
RHODOZYMA YEAST OF ENHANCED ASTAXANTHIN CONTENT

SECOND DECLARATION OF STEPHEN HIU
UNDER 37 C.F.R. § 1.132

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Stephen Hiu, hereby declare and state:

My position at IGENE, assignee of the above application, has not changed from my previous Declaration filed 1 April 1998 and executed by me on 7 November 1997 (hereinafter "Declaration").

I hold a Ph.D. degree and have training in microbiology, fermentation and biochemistry.

My curriculum vitae is attached hereto.

In the Office Action of 29 July 1998, the Examiner raised issues relating to enablement of the subject matter and description of the subject matter.

Regarding enablement, I have read the specification and am convinced the application provides a reproducible teaching of how to make and how to use a mutant Phaffia which overproduces astaxanthin.

There is a patent directed to the making of such a mutant Phaffia. The starting strains of Phaffia are available without

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DECLARATION UNDER 37 C.F.R. §1.132
U.S. Appln. No.: 08/458,019

restriction, the reagents for culturing and treating the yeast are commercially available and the methods of obtaining a mutant *Phaffia* as claimed are provided in the application, and as mentioned above, one such usable method is patented.

To demonstrate the enabling nature of the claimed invention, the Rule 132 Declaration previously filed demonstrated the development of over 100 examples of mutant *Phaffia* overexpressing astaxanthin practicing the teachings provided in the earliest filed application in the family, U.S. Serial No. 229,563 filed 8 August 1988. There was and is no reason or need to resort to any further or undue experimentation.

The claimed invention relates to a specific type of yeast, *Phaffia*, and relates to a specific, readily definable characteristic of that yeast. Many working examples are provided in the application; numerous examples of astaxanthin overproducing *Phaffia* are provided in the application; and my earlier Declaration demonstrated the ready reproducibility of the methods taught in the application and the many other examples of *Phaffia* containing enhanced levels of astaxanthin so obtained.

A key feature of the Declaration evidence is that each of the over 100 additional examples of *Phaffia* which overproduce astaxanthin was made according to the teachings of the specification of the earliest parental application, U.S. Serial No. 07/229,536 filed 8 August 1988 and existed prior to that 8 August 1988 filing date.

DECLARATION UNDER 37 C.F.R. §1.132
U.S. Appln. No.: 08/458,019

Therefore, the specification is indeed enabling as to Phaffia with enhanced astaxanthin content as of the 8 August 1988 earliest filing date in the patent family.

Regarding the written description issue, as stated hereinabove, the description of the application clearly allows one of ordinary skill in the art to recognize what was invented and what is claimed. The specification conveys with clarity, that as the filing of the earliest parental application, 8 August 1988, the inventors had indeed made and used Phaffia with enhanced astaxanthin content.

Examples of Phaffia with enhanced astaxanthin content are provided in the specification. Those numerous examples of yeast were made by, for example, the method provided in one of the patents which matured from an earlier application in the family.

That the invention is clearly conveyed to those skilled in the art at the time U.S. Serial No. 07/229,536 filed is supported not only by the actual examples of Phaffia recited in the specification but also by my earlier Declaration which provides evidence that practicing the invention as provided in the specification, more than 100 examples of the claimed Phaffia were obtained prior to the 8 August 1988 filing of U.S. Serial No. 07/229,536.


Therefore, I am convinced that an artisan would know on reading the specification of U.S. Serial No. 07/229,536 that the named inventors were in full possession of the now claimed invention.

DECLARATION UNDER 37 C.F.R. §1.132
U.S. Appln. No.: 08/458,019

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Further Declarant sayeth not.

Date: 10/29/98


Stephen Hsu